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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,267	STAGLIANO ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 22, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply, filed May 22, 2007, which amends claims 1 and 7, and cancels claims 12-20. Currently, claims 1-11 are under examination.

Claim Rejections - 35 USC § 101

Section 101 of 35 U.S.C. reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claim 1 is directed to a method of detecting binding between a "compound" and a polypeptide corresponding to SEQ ID NO:20. According to Applicants' disclosure, such a "compound" is potentially specifically useful for treating disease.

Applicants' asserted utility is based on observations concerning a ***nucleic acid*** corresponding to SEQ ID NO:19. Applicants detected[1] nucleic acid corresponding to SEQ ID NO:19 in various animal cells, and observed that the detected amounts of nucleic acid corresponding to SEQ ID NO:19 fluctuated in response to added chemicals, including cholesterol, fatty acid, Mevastatin, or Cerivastatin.

Applicants assert:

1. a nucleic acid corresponding to SEQ ID NO:19 "plays a role" in lipid metabolism.

[1] Applicants detected nucleic acid corresponding to SEQ ID NO:19 using standard nucleic acid amplification techniques (*i.e.*, TaqMan™ RT-PCR).

2. a ***polypeptide*** corresponding to SEQ ID NO:20 "potentially plays a direct role" in cholesterol metabolism and/or lipid metabolism.
3. a compound that binds to a *polypeptide* corresponding to SEQ ID NO:20 is useful for treating disease.

According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic underlying Applicants' assertion. In other words, credibility refers to the reliability of Applicants' assertion of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.

Here, Applicants' asserted utility is not credible because Applicants' specification fails to disclose any data in support of assertion 2), *supra*.[2] That is, Applicants' specification does not disclose any evidence[3] of any polypeptide, much less a polypeptide corresponding to SEQ ID NO:20, potentially "playing" any "role" in any metabolic system.

A claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.[4] A patent is not a hunting license.[5]

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[2] Please note, Examiner does not contest the notion that persons skilled in the art routinely practice the methods generally described in Applicants' specification for screening compounds. However, for the reasons set forth herein, Examiner does contest the quality and/or quantity of data regarding the specific application of those routinely practiced methods used to derive Applicants' claimed invention. Examiner posits that, based on the quantity of data (none) found in Applicants' disclosure, persons skilled in the art could not reasonably conclude that a polypeptide corresponding to SEQ ID NO:20 has utility for anything other than future characterization and validation studies. These further studies, however, are part of the act of invention and until performed, Applicants' claimed invention is incomplete.

[3] According to Veenstra, 3 DRUG DISCOVERY TODAY 433 (2006), a determination of whether a polypeptide is a "deranged protein" that "plays a role" in a disease requires, *inter alia*, performing: (1) correlating RNA abundance versus protein abundance; (2) selecting suitable protein-containing samples; (3) optimizing fractionation protocols; (4) optimizing protein assays; (5) purifying pure protein; (6) performing preliminary binding assay; and (7) identifying structurally modifiable binding determinants (if any).

[4] See MPEP 2107.01. A product invention lacks substantial utility if further research is necessary to study the properties of the product, so that a "real world" use may be identified or confirmed.

[5] See *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689, 696 (US SupCt 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 7, the passive voice phrase "a test compound[...] is identified" (paraphrasing mine) is indefinite. The identity of one or more objects or steps, if any, required for "identifying" is not clear and appear omitted from the claim. Whether one or more steps of "identifying" are completed, performed, or merely intended is not clear.

Response to Arguments

In prior Office Action, claims 1-11 were rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

In response, Applicants amend independent claim 1 further qualifying the claimed method to identifying a "potentially useful" compound. In addition, Applicants allude to "evidence of record" tending to support Applicants' asserted utility (see *e.g.*, Applicants' reply, paragraph bridging pp. 7-8, first sentence).

Applicants' arguments have been carefully considered but are not persuasive.

Examiner acknowledges Applicants' amendment to independent claim 1 further qualifying the claimed method to identifying a "potentially useful" compound. However, a claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.[6]

As for Applicants' purported "evidence of record", Examiner is unable to identify such "evidence of record" supporting Applicants' asserted utility. [7,8] As set forth in the instant and prior Office Action, Applicants' asserted utility is not credible because Applicants' specification fails to substantiate the existence of a polypeptide corresponding to SEQ ID NO:20 playing a role in treating a cardiovascular/thrombotic disorder. More importantly, Applicants' specification fails to substantiate the existence of a compound that binds to a polypeptide corresponding to SEQ ID NO:20 useful for treating a cardiovascular/thrombotic disorder. Finally, Applicants' specification fails to substantiate any of Veenstra's seven factors set forth in

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[6] See *supra*, note 4. Examiner posits that many different compounds are "potentially useful" for treating many different diseases. However, not all methods for identifying "potentially useful" compounds are necessarily useful.

[7] According to M.P.E.P. § 716.01(c), Applicant must factually support any objective evidence with an appropriate affidavit or declaration to be of probative value. As such, Examiner requests Applicants to provide such an affidavit or declaration that, at the very minimal, addresses Applicants' purported "evidence of record".

[8] In other words, Applicants do not identify such "evidence of record" tending to support the existence of a polypeptide corresponding to SEQ ID NO:20 playing a role in treating a cardiovascular/thrombotic disorder. More importantly, Applicants do not

footnote 3 of the instant and prior Office Action, which according to Veenstra, are required for a credible determination of whether a polypeptide is a "deranged protein" that "plays a role" in a disease.

identify such "evidence of record" tending to support the existence of a compound that binds to a polypeptide corresponding to SEQ ID NO:20 useful for treating a cardiovascular/thrombotic disorder.

Conclusion

No claims are allowable at this time.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Assistant Examiner
Art Unit 1641

djv

LONG V. LE 08/06/07
SUPERVISORY PATENT EXAMINER
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